IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: RESPIRONICS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	Master Docket: Misc. No. 21-1230
This Document Relates to: All Actions	MDL No. 3014

MEMORANDUM OPINION

I. Introduction

Pending before the court are: (1) (ECF No. 2314) plaintiffs' objections to the Special Master's[1] report and recommendation ("R&R") (ECF No. 2273) on the motion to dismiss the Complaint for Medical Monitoring (the "Med Mon Master complaint") (ECF No. 1351) filed by defendant Philips RS North America, LLC ("Respironics")[2]; and (2) (ECF No. 2316) Respironics' objections to the R&R. The objections and underlying motion to dismiss are fully briefed.

II. Factual and Procedural Background

This is a multi-district litigation ("MDL") involving CPAP, Bilevel PAP, and mechanical ventilator products. On October 17, 2022, plaintiffs filed a consolidated second amended class

[1] On January 18, 2023, the court appointed the Honorable Thomas I. Vanaskie (the "Special Master") to serve as a Special Master (ECF No. 1434).
[2] The motion to dismiss and Respironics' objections to the R&R were filed only on behalf of Respironics.

action complaint for medical monitoring (ECF No. 815). There are two other master complaints in this MDL: a personal injury master complaint (the "Master PI complaint"); and an economic loss master complaint.[3] Plaintiffs' counsel, at a hearing on January 25, 2024, concerning discovery matters, explained that the Master PI complaint contained claims similar to the claims asserted in the Med Mon Master complaint, with the difference between those similar claims being that the named plaintiffs and putative class members in the PI Master complaint allege manifest personal injury, while in the Med Mon Master complaint no named plaintiff or putative class member alleges a manifest personal injury; rather, they allege subcellular physical injury and economic losses. (Transcript, ECF No. 2481 at 53).[4] In other words, the Med Mon Master complaint involves a subset of 69 named plaintiffs and putative class members who seek medical monitoring – either as a stand-alone claim or as a form of relief under some other claim – without alleging a manifest personal injury. *See* Tr., ECF No. 2481 at 44 ("[T]his claim specifically is not an injury claim and the claim here is that all of our plaintiffs are not injured . . . .").

As noted, in the Med Mon Master complaint the named plaintiffs, individually and on behalf of the putative class members, assert subcellular injuries.[5] Plaintiffs allege that they inhaled or ingested foam toxins which were absorbed into tissue and their blood stream (ECF No. 815 ¶ 367); certain of the toxins are toxic or carcinogenic to humans, ¶ 368; persistent exposure results

[3] The parties reached a class action settlement on the economic loss claims, which is pending final approval by this court (ECF No. 2287).

[4] Due to a concern about claim-splitting, the Master PI complaint (count XX) also seeks medical monitoring. Plaintiffs and Respironics both recognize that whenever a claim is asserted in both master complaints, whatever decisions the court makes with respect to a motion to dismiss a claim in one master complaint will apply to the asserted claim in the other master complaint.

[5] Plaintiffs cite to ¶¶ 266-79, 538 of the Med Mon Master complaint as the basis for their subcellular injury allegations (ECF No. 2314 at 11). Those citations are likely a clerical error; the court understands that the relevant allegations are at ECF No. 815 ¶¶ 367-371.

in their presence, accumulation, toxic invasion and persistence in human tissues and the bloodstream, ¶ 370; and the toxins are cytotoxic and genotoxic and exposure causes widespread damage to DNA as well as other critical systems of the human body, ¶ 371. Based on scientific literature, exposure to the foam toxins places plaintiffs at increased risk of developing numerous serious illnesses, ¶ 371. Plaintiffs' counsel explained there will be no medical records diagnosing a subcellular injury, but there will be expert testimony. (Tr., ECF No. 2481 at 51).

The Med Mon Master complaint is 222 pages long and contains 15 counts asserting individual and class claims. Plaintiffs, among other things, allege a nationwide class of all persons in the United States who have used a Recalled Device at least 30 times. (ECF No. 815 ¶ 387). Plaintiffs' counsel stated at the hearing held on January 25, 2024, that they may ask the court at the time of class certification to apply Pennsylvania law to the nationwide class. (ECF No. 2481 at 33). In addition or in the alternative, Plaintiffs allege 40 state subclasses; each subclass consists of persons in a particular state who used a Recalled Device at least 30 times. (ECF No. 815 ¶¶ 389-429).[6]

The Med Mon Master complaint asserts 15 counts containing various claims on behalf of individual plaintiffs, the nationwide class and various state subclasses. The claims can be grouped into five kinds of claims: (1) traditional tort claims (Counts I-III, V-IX, XIII)[7]; (2) a stand-alone tort claim for medical monitoring in the states in which a stand-alone claim is recognized (Count IV); (3) contractual breach of warranty claims (Counts X-XII)[8]; (4) products liability statutory claims (Count XIV); and (5) a declaratory judgment claim (Count XV).

[6] There are 10 states in which there are no named plaintiffs.
[7] Negligence, negligence per so, negligent misrepresentation, products liability-design defect, negligent design, strict liability-failure to warn, and negligent recall/negligent failure to recall and fraud).
[8] Breach of implied warranty of merchantability, breach of implied warranty of usability and breach of express warranty.

On January 6, 2023, Respironics filed a motion to dismiss the Med Mon Master complaint in its entirety, and a brief in support (ECF Nos. 1351, 1352). Plaintiffs filed a response and brief in opposition to the motion (ECF Nos. 1633, 1634) and Respironics filed a reply (ECF No. 1828).

On January 31, 2023, the court referred Respironics' motion to dismiss the Med Mon Master complaint to the Special Master for a report and recommendation. The order appointing the Special Master specified, in relevant part, that: (1) the failure to file a timely objection shall constitute a waiver of any objection; and (2) the report and recommendation will be reviewed by the court de novo. (ECF No. 1434 ¶¶ 16, 17). Pursuant to Federal Rule of Civil Procedure 53(f)(1), the court "may adopt or affirm, modify, wholly or partly reject or reverse, or resubmit to the master with instructions."

The Special Master heard in-person oral arguments on July 10-11, 2023, which the court attended. On September 28, 2023, the Special Master filed the R&R (ECF No. 2273), which recommended that Respironics' motion to dismiss the Med Mon Master complaint be granted in part and denied in part. In essence, the Special Master recommended that the motion to dismiss be granted with respect to tort claims under the laws of 30 states which adhere to the traditional "manifest physical injury" rule and be denied in all other respects. Plaintiffs and Respironics filed timely objections to the R&R. The court reviewed the R&R and the submissions of plaintiffs and Respironics de novo.

III. Discussion

A. The need to resolve the claims asserted in the Med Mon Master complaint

The Special Master addressed the disputes presented to him by the parties. The parties, however, did not provide the Special Master a clear state by state roadmap of which element or elements of the claims asserted are or are not at issue for the purpose of resolving the motion to dismiss. States have taken different approaches to medical monitoring. At the motion to dismiss stage, a thorough survey of the pertinent elements of each claim asserted in the Med Mon Master complaint and each state's law must be conducted to determine whether a stand-alone claim is plausibly stated for medical monitoring or if any other claim is plausibly stated for which medical monitoring may be obtained as a form of relief. The time invested now in precisely identifying the applicable claims and law in each state will pay dividends in guiding discovery and narrowing the disputes.

The court will not adopt the R&R and will remand, i.e., resubmit, the motion to the Special Master to conduct this analysis and file a revised report and recommendation with the benefit of the guidance set forth in the following discussion.

B. Tort claims

1. Overview of differing medical monitoring approaches with respect to tort claims

"Medical monitoring is a controversial concept that has not undergone widespread scrutiny in the state courts, let alone gained widespread acceptance." 1 *McLaughlin on Class Actions* § 5:18 (20th ed.) (Oct. 2023 update). The majority of the highest courts in the states have not addressed medical monitoring. Some states recognize a separate, stand-alone claim for medical monitoring. Other states view medical monitoring as a kind of relief that may be obtained for a separate claim. *Id.* The distinction has practical consequences. As the treatise explained: "If

medical monitoring is not an independent cause of action, then the plaintiff must establish all elements of an independent basis of recovery, and the defendants may assert all available affirmative defenses." *Id.*

The elements to obtain medical monitoring differ among states, although the elements do not appear to vary based on whether medical monitoring is a stand-alone claim or a kind of relief for a separate claim.[9] *Id.* As discussed below, some states require a plaintiff to show the existence of physical harm; other states do not. *Id.* In this case, plaintiffs and Respironics dispute whether subcellular change can satisfy the need to show physical harm. Some states require that manifest personal injury be alleged. Some states require proof of an increased risk of future injury; other states require proof of a "significantly" increased risk of future injury. *Id.* Some states require that treatment for the plaintiff's ailment exist; other states have expressly eliminated that requirement. *Id.*

In this case, the Special Master explained that plaintiffs contend the states in issue fall into 3 categories that can be treated as state subclasses: (1) 14 states that explicitly held that medical monitoring can be obtained without a manifest physical injury; (2) 23 states that have not explicitly addressed medical monitoring but would follow Restatement (Second) of Torts § 7 to hold that a pecuniary loss due to medically necessary diagnostic testing satisfies the actual injury requirement; and (3) 5 states that have explicitly addressed medical monitoring, have not decided whether a pecuniary loss due to medically necessary diagnostic testing satisfies the actual injury requirement, but would follow Restatement (Second) of Torts § 7. (ECF No. 2273 at 5-6). These categories appear to relate to the tort claims asserted in the Med Mon Master complaint.

[9] Even among states that recognize medical monitoring as an independent cause of action, some states impose a negligence standard, while others allow medical monitoring on proof of other tortious conduct, which could include strict liability. *Id.*

In *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990), the Third Circuit Court of Appeals predicted that the Supreme Court of Pennsylvania would recognize a stand-alone claim for medical monitoring with the following elements:

1. Plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant.

2. As a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease.

3. That increased risk makes periodic diagnostic medical examinations reasonably necessary.

4. Monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial.

Id. at 852. The Special Master determined that plaintiffs alleged each of these elements (ECF No. 2273 at 13-25).[10] Respironics did not object to that determination. Respironics asserts, however, that plaintiffs cannot obtain medical monitoring under the laws of most states (either as a stand-alone claim or as a remedy for another legal theory) without establishing a manifest physical injury.

2. Split of authority about requirement for manifest physical injury for tort claims

One element of a tort claim is typically that there be injury. *See Baker v. Croda Inc*., No. 393, 2022, 2023 WL 5517797, at *2 (Del. Aug. 24, 2023) ("It is axiomatic that all tort claims require an injury.").

There is a split of authority about whether a manifest physical injury should be required to establish entitlement to medical monitoring (either as a stand-alone claim or to satisfy the injury element with respect to claims where it is sought as a remedy). There are compelling policy

[10] The Special Master did not examine the elements of a prima facie case for medical monitoring under the laws of other states.

arguments for allowing medical monitoring while a potential disease is latent. In *Baker v. Saint-Gobain Performance Plastics Corp*., 232 F. Supp. 3d 233 (N.D.N.Y. 2017), aff'd in part, appeal dismissed in part, 959 F.3d 70 (2d Cir. 2020), the court commented:

> [R]equiring plaintiffs to manifest physical symptoms before receiving medical monitoring would defeat the purpose of that remedy. The entire point of medical monitoring is to provide testing that would detect a patient's disease before she manifests an obvious symptomatic illness, thus allowing earlier treatment that carries a better chance of success. *Abbatiello*, 522 F.Supp.2d at 536; *Guzelian et al*., supra, at 64, 76–77. "Medical monitoring" provides small comfort to someone already suffering outwardly apparent symptoms if the only benefit is to track the continued advance of the disease. Further, the cost of testing necessary to provide treatment would already be recoverable as a component of damages arising from the illness itself.

Id. at 252.

On the other hand, the contours and scope of a stand-alone claim for medical monitoring is difficult to discern. In *Caronia v. Philip Morris USA, Inc*., 5 N.E. 3d 11 (N.Y. 2013), the court articulated some of the concerns and concluded that the issue was better suited for the legislature to resolve:

> Plaintiffs ask us to follow the second line of cases—*Donovan* in particular—and recognize a cause of action for medical monitoring because Philip Morris's "wrong," i.e., its alleged failure to design a safer cigarette that delivers lower amounts of tar, should not be without a remedy. Although "the desire to provide an avenue to redress wrongs is ... an important consideration underlying our tort jurisprudence, the recognition that there has been an interference with an interest worthy of protection has been the beginning, not the end, of our analysis" (*Ortega v. City of New York*, 9 N.Y.3d 69, 78, 845 N.Y.S.2d 773, 876 N.E.2d 1189 [2007]). This Court undoubtedly has the authority to recognize a new tort cause of action, but that authority must be exercised responsibly, keeping in mind that a new cause of action will have both "foreseeable and unforeseeable consequences, most especially the potential for vast, uncircumscribed liability" (*Madden v. Creative Servs.*, 84 N.Y.2d 738, 746, 622 N.Y.S.2d 478, 646 N.E.2d 780 [1995] [citations omitted]).
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> From a practical standpoint, it cannot be overlooked that there is no framework concerning how such a medical monitoring program would be implemented and

> administered. Courts generally lack "the technical expertise necessary to effectively administer a program heavily dependent on scientific disciplines such as medicine, chemistry, and environmental science" (*Henry*, 473 Mich. at 91–92, 701 N.W.2d at 698–699). The legislature is plainly in the better position to study the impact and consequences of creating such a cause of action, including the costs of implementation and the burden on the courts in adjudicating such claims (*see* Schwartz, Medical Monitoring: The Right Way and the Wrong Way, 70 Mo. L. Rev. at 382–385).

Id. at 17-18.

The Delaware Supreme Court recently answered a certified question from the Third Circuit Court of Appeals about whether medical monitoring can be obtained as a remedy under Delaware tort law absent a manifest physical injury:

> [A]n increased risk of illness without physical harm is not a cognizable injury under Delaware law. Stated differently, an increased risk of harm only constitutes a cognizable injury once it manifests in a physical disease. It is axiomatic that all tort claims require an injury. Under Delaware law, an "injury in fact" is defined as "an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." An increased risk of illness, without more, is not "actual or imminent," and thus does not constitute an injury.

Baker v. Croda Inc., No. 393, 2022, 2023 WL 5517797, at *2 (Del. Aug. 24, 2023).

B. Positions of the parties

As an initial matter, plaintiffs and Respironics agree that the reference to "Count IV" in the recommendation (ECF No. 2273 at 38) is confusing and is inconsistent with the discussion in the report. They each seek clarification. In count IV, plaintiffs seek medical monitoring for a nationwide class, asserting a stand-alone claim under Pennsylvania law and for separate state subclasses as recognized under the laws of 11 states.[11] Plaintiffs explain that with respect to the

[11] Count IV asserts state subclasses for stand-alone medical monitoring claims under the laws of 11 jurisdictions: Colorado, Connecticut, Delaware, District of Columbia, Florida, Massachusetts, Montana, New Hampshire, Pennsylvania, Utah, and West Virginia. ECF No. 815 at 174. Plaintiffs withdrew their stand-alone claims under Delaware and New Hampshire law (ECF No. 2368 at 6 n.2). The Special

other claims in the Med Mon Master complaint (with the exception of the declaratory judgment in count 15), they seek medical monitoring as a remedy (i.e., recoverable damages for an underlying cause of action) for the relevant classes.

Plaintiffs assert several different legal theories based on variations in state law: (1) the need to undergo medical monitoring is a pecuniary harm (i.e., a financial injury); (2) physical injury is not required; (3) the physical injury requirement is satisfied by the allegation of subcellular injury; and (4) under count IV for the nationwide class, Pennsylvania law, which recognizes a stand-alone claim for medical monitoring, extraterritorially applies. Plaintiffs challenge the Special Master's blanket dismissal of state law claims where the state's highest court has not recognized a negligence-based claim for medical monitoring absent physical injury. Plaintiffs contend that the Special Master did not address their subcellular injury theory in each relevant state. Plaintiffs also contest the Special Master's specific analysis in numerous states, relying heavily on the decision in *In re Valsartan, Losartan, & Irbesartan Products Liability Litigation*, No. 19-2875, 2023 WL 1818922, at *1 (D.N.J. Feb. 8, 2023) ("*In re Valsartan*").

Respironics maintains that the Med Mon Master complaint should be dismissed in its entirety, but asserts only the following "narrow objections to the R&R": (1) consistent with the Special Master's reasoning, all medical monitoring claims in the 28 remaining "disputed jurisdictions" which the Special Master determined require a manifest phyisical injury should be dismissed; (2) abandoned claims or requests for relief (for a science panel and 10 states where no named plaintiff resides) should be dismissed; (3) similar claims dismissed on other grounds in the Master PI Complaint (*see* Opinion and Order ECF Nos. 1471, 1472), should be dismissed in

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Master recommended that the stand-alone claims under Connecticut, Colorado and Montana law be dismissed for other reasons. (ECF No. 2273 at 26). The R&R contains a confusingly similar list of 11 states that do not require a manifest physical injury (ECF No. 2273 at 4 n.3), which differs from the list of 11 states that recognize a stand-alone claim, as pleaded in count IV of the Med Mon Master complaint.

the Med Mon Master complaint; (4) the Special Master erred in his recommendation about Tennessee law; (5) the product liability act claims should be dismissed; and (6) the declaratory judgment claim should be dismissed.[12]

C. The reference to "count IV" (stand-alone medical monitoring claims)

Respironics suggests that the reference to count IV at page 38 of the R&R may be a "simple clerical error." (ECF No. 2316 at 7). Respironics points out that 9 of the states listed in count IV are not among the 30 states for which the Special Master recommended dismissal in his analysis (ECF No. 2273 at 7-9). Plaintiffs agree that the reference to count IV on page 38 is confusing. Plaintiffs appear to understand that the Special Master recommended dismissal of their medical monitoring claims in 30 states (and object to that recommendation for 28 of those states)[13] (ECF No 2314 at 6).

The court agrees that the reference to count IV on page 38 of the R&R was inadvertent. The Special Master's reasoning clearly reflected a recommendation that medical monitoring cannot be obtained as a remedy under the laws of the 30 states listed in the R&R because the highest courts in those jurisdictions "have not recognized a negligence-based claim for medical monitoring absent physical injury." (ECF No. 2273 at 7). The Special Master recommended that the court grant Respironics' motion to dismiss the claims for medical monitoring in those 30 states. *Id.* at 7-8. The reference to "count IV" (ECF No. 2273 at 38) will be disregarded as inadvertent.

[12] Respironics did not object to the Special Master's recommendation about Massachusetts law (ECF No. 2273 at 10-13).

[13] Plaintiffs do not challenge the Special Master's recommendation of dismissal with respect to claims for medical monitoring asserted under the laws of North Carolina and New Hampshire (ECF No. 2314 at 7 n. 2). The Special Master recommended that medical monitoring relief can be obtained under Tennessee law.

D. Abandoned relief and claims

The Special Master noted that plaintiffs are no longer seeking an independent science panel and that plaintiffs conceded that their claims are not justiciable in the 10 states in which no named plaintiff resides (ECF No. 2273 at 2 n.2). Plaintiffs do not directly object to this part of the R&R, although they explain that they seek medical monitoring for a nationwide class in count IV based on extraterritorial application of Pennsylvania law in all jurisdictions (ECF No. 2368 at 13). The extraterritoriality of Pennsylvania law was not raised in Respironics' motion to dismiss or addressed by the Special Master and will need to be addressed at the class certification stage of the proceeding. The request for a science panel will be recognized as abandoned and claims asserted under the laws of the 10 states with no named plaintiff will be dismissed without prejudice. On remand, the Special Master should directly address which claims under which counts fall within that situation.

E. Claims dismissed in the PI Master complaint

Respironics argues that to the extent similar claims are dismissed, for other reasons, in the analysis of the Master PI complaint, those claims should also be dismissed in the Med Mon Master complaint. Plaintiffs agree with the principle that dismissal of overlapping substantive claims should be consistently applied (ECF No. 2368 at 14). Plaintiffs argue that it is premature to make such determinations because they intend to amend the Master PI complaint. The court permitted the filing of an amended Master PI complaint (ECF No. 2472). Counsel shall meet

and confer to accomplish the consistent dismissal of overlapping claims after the resolution of any motions to dismiss the contemplated amended Master PI complaint.[14]

F. Duty to interpret, not expand, state law

The parties' primary legal dispute involves the extent of this court's latitude to predict state law. Respironics asserts the principle that this court must adopt the interpretation that minimizes liability. Plaintiffs argue that the Special Master inappropriately required an on-point decision from the state's highest court, rather than making a reasonable prediction of state law.

The Special Master followed the principles set forth in *City of Philadelphia v. Lead Industry Association, Inc*., 994 F.2d 112 (3d Cir. 1993), which recognized certain constraints on federal courts in making predictions of state law:

> When the state's highest court has not addressed the precise question presented, a federal court must predict how the state's highest court would resolve the issue, *Borman v. Raymark Indus., Inc*., 960 F.2d 327, 331 (3d Cir.1992); *Pennsylvania Glass Sand Corp. v. Caterpillar Tractor Co.*, 652 F.2d 1165, 1167 (3d Cir.1981), and is not free to shape state common law as it sees fit, *Adams v. Madison Realty & Dev., Inc.*, 853 F.2d 163, 168 (3d Cir.1988). "A federal court in a diversity case is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court, but which have not commended themselves to the State in which the federal court sits." *Day & Zimmermann, Inc. v. Challoner*, 423 U.S. 3, 4, 96 S.Ct. 167, 168, 46 L.Ed.2d 3 (1975).
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> A federal court may act as a judicial pioneer when interpreting the United States Constitution and federal law. In a diversity case, however, federal courts may not engage in judicial activism. Federalism concerns require that we permit state courts to decide whether and to what extent they will expand state common law. *See Wisniewski v. Johns–Manville Corp*., 759 F.2d 271, 274 (3d Cir.1985) ("We leave to ... the state legislatures and, where relevant, to the state courts the task of expanding or restricting liability for asbestos production."); *Bruffett v. Warner Communications, Inc*., 692 F.2d 910, 920 (3d Cir.1982). Our role is to apply the current law of the appropriate jurisdiction, and leave it undisturbed.

[14] For example, tort claims asserted in the Master PI complaint which are subsumed by products liability statutory claims in a pertinent state would likewise be subsumed for purposes of the Med Mon Master complaint.

Id. at 113. In making its prediction of state law, the court must consider several things:

> An authoritative signal that a state's highest court would modify existing state law may be gleaned from lower state court decisions, the decisions of other courts, and treatises or other scholarly works. *See Pennsylvania Glass Sand*, 652 F.2d at 1167. Although not dispositive, decisions of state intermediate appellate courts should be accorded significant weight in the absence of an indication that the highest state court would rule otherwise.

Id. at 123.

In *City of Philadelphia*, in the context of negligence, products liability, breach of warranty and fraud claims, the court concluded that, where there were policy arguments for and against the adoption of market share liability, one trial court decision and dicta from several Pennsylvania Superior Court decisions did not provide a clear signal that Pennsylvania would adopt the market share theory of liability. *Id.* at 125. The court noted that federal district courts endorsing Pennsylvania's adoption of the market share theory had "jumped ahead of the current state of Pennsylvania law" and reiterated that a federal court should not "perform the expansion" of state law. *Id.* at 125 n. 12. The court observed: "We are unsure how the Pennsylvania Supreme Court would balance the policy arguments favoring and militating against the adoption of market share liability. We are certain, however, that a federal court in a diversity case should not perform the delicate balancing act for it." *Id.* at 126. The court's "conviction [was] strengthened by the numerous disparate versions of market share liability in existence." *Id.* In this case, similarly, deference may be appropriate when state supreme courts, for policy reasons, have adopted several disparate approaches to medical monitoring -- making predictions about how another state's highest court would rule more difficult.

City of Philadelphia remains good law and represents binding precedent within the Third Circuit. The court must consider numerous sources to predict state law, but it is not this court's role to expand state law. *See Bruffett v. Warner Commc'ns, Inc.*, 692 F.2d 910, 920 (3d Cir.

1982) ("One of the authentic obligations of federalism at the judicial level requires that we permit the state courts to decide whether and to what extent they will follow the emerging law."). As explained in *City of Philadelphia*, a federal court in a diversity case "may not significantly expand state law without a **clear indication** that the Pennsylvania Supreme Court would do the same." 994 F.2d at 115 (emphasis added).[15]

This court's analysis of other federal court decisions predicting state law must be somewhat nuanced. On one hand, a mere unsupported pronouncement by a federal court about what a state's law should be may not alone be sufficient to serve as the requisite clear indication of state law. On the other hand, a thorough analysis by a federal district court based on the predictive principles set forth in *City of Philadelphia* and progeny may be a persuasive indication about what a state's supreme court would do. Indeed, this court may consider, among other things, decisions of federal courts. *Spence v. ESAB Grp., Inc.*, 623 F.3d 212, 216–17 (3d Cir. 2010) ("In making such a prediction, 'we must look to decisions of state intermediate appellate courts, of federal courts interpreting that state's law, and of other state supreme courts that have addressed the issue,' as well as to 'analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand.'"); *City of Philadelphia*, 994 F.2d at 123. In other words, another federal court's thorough analysis to predict state law may be quite helpful when this court undertakes the same task. In *Spence*, the court reiterated that federal courts may "not impose our own view of what state law should be nor expand state law in ways not foreshadowed by state

[15] In addressing the objections to the R&R about the Master PI complaint, the court declined Respironics' suggestion that this court should predict that Pennsylvania law would categorically apply Restatement (Second) of Torts § 402A comment k to prescription medical devices. The court observed that Respironics was asking the court to take a step that Pennsylvania courts had not yet taken. (ECF No. 2471 at 16).

precedent." *Spence*, 623 F.3d at 217 (citation omitted).[16] The court finds persuasive the Special Master's R&R with respect to how a court should predict state law (ECF No. 2273 at 6-7), as supplemented herein.

Plaintiffs contend that the Special Master erred in recommending dismissal of claims asserted under the laws of 5 jurisdictions (Hawaii, Maine, New Mexico, Puerto Rico and South Carolina) despite the lack, in those jurisdictions, of any caselaw about medical monitoring (ECF No. 2314 at 20). Plaintiffs argue that those jurisdictions have a history of following the Restatement (Second) of Torts and that this court should adopt the approach in *In re Valsartan* and "err on the side of liberal pleading." (ECF No. 2314 at 20). A court, however, must be mindful for tort-based claims that "whether an increased risk of illness, without present manifestation of a physical harm, is a cognizable injury" is a matter of substantive state law. *See Baker v. Croda Inc.*, No. 21-3360, 2022 WL 19010312, at *1 (3d Cir. Oct. 21, 2022) (certifying question to Delaware Supreme Court), *certified question answered*, No. 393, 2022, 2023 WL 5517797 (Del. Aug. 24, 2023). Where there are such divergent policies among the states, the complete absence of authority in a disputed jurisdiction probably will not serve as "clear indication" that the relevant state would abandon the traditional rule and expand tort liability with respect to medical monitoring.

[16] In *In re Valsartan*, 2023 WL at 1818922, a federal district court surveyed state variations in medical monitoring law. That decision, however, involved class certification, not a motion to dismiss. The *Valsartan* case (MDL No. 19-2875), like this case, was an MDL in which the court permitted three master complaints to be filed (for economic loss, personal injury and medical monitoring). The court appears to have issued four prior opinions on motions to dismiss, at least one of which involved, among other things, a motion to dismiss stand-alone medical monitoring claims. *In re Valsartan*, MDL No. 19-2875, 2021 WL 364663 at *10, *23-25 (D.N.J. Feb. 3, 2021) (referring to MTD Opinion 2 and MTD Opinion 3). No party brought to the attention of the Special Master the decisions in the *Valsartan* case relating to the motions to dismiss. On remand, the parties should analyze those decisions for the Special Master's review to the extent they would be helpful in determining his recommendation about how this court should predict a state's law on any particular issue.

G. Statutory Products Liability claims

Respironics argues that the products liability act claims arising under the laws of 7 states must be dismissed for failure to allege a personal injury. The Special Master recommended that these claims survive based on the allegation of a subcellular injury (ECF No. 2273 at 27-35). The Special Master did not explain his reasoning or address the elements of the claims implicated.

In particular, the Special Master did not address Respironics' argument based on *Sinclair v. Merck & Co*., 948 A.2d 587 (N.J. 2008) (involving claimed risk of future cardiovascular injury from exposure to Vioxx, without present symptoms), in which the law in the 7 contested states (Connecticut, Indiana, Kansas, New Jersey, Ohio, Tennessee and Washington) was surveyed. *Id.* at 594 n. 1 (observing that the products liability acts in each of the states at issue require a physical injury). The question in *Sinclair* was whether the plaintiffs had suffered "harm" as defined in the relevant products liability act to be able to recover monitoring damages. The court held a "claimed risk of future cardiovascular injury was not cognizable under the PLA because the statute "require[s] a physical injury." *Id.* at 595.

Plaintiffs recognize that *Sinclair* requires a physical injury, but contend that it did not resolve whether an allegation of subcellular injury would suffice. Respironics argues that this is another issue on which this court must defer to each state's determination of its own law. *See City of Philadelphia*, 994 F.2d at 113. The Special Master cited *Sinclair*, but did not analyze it or apply it to each of the states at issue (ECF No. 2273 at 32). On remand, the Special Master should consider whether there is a clear indication that any of the states at issue would adopt a "subcellular injury" basis for "harm" in construing their products liability acts.

H. Declaratory judgment claim

Plaintiffs are the masters of their complaint. They contend that they seek a declaration about Respironics' future conduct. In exercising its discretion to hear a declaratory judgment claim, 28 U.S.C. § 2201, a court considers: "(1) the likelihood that a federal court declaration will resolve the uncertainty of obligation which gave rise to the controversy; (2) the convenience of the parties; (3) the public interest in settlement of the uncertainty of obligation; and (4) the availability and relative convenience of other remedies." *Baker v. Deutschland GmbH*, 240 F. Supp. 3d 341, 350 (M.D. Pa. 2016) (citation omitted). At this stage of the case, the declaratory judgment claim appears plausible. *See id.* ("It would be premature to dismiss the declaratory judgment action because, without factual development of the medical monitoring claim, it is unclear whether a declaration of defectiveness would be a useful clarification by the Court.").

I. Remand to Special Master

The motion to dismiss the Med Mon Master complaint will be resubmitted to the Special Master for further consideration and to issue a revised R&R. The court will not address the parties' specific disputes about various states' laws at this time; in part, because it is unclear which counts of the Med Mon Master complaint would be affected. Instead, the court will address any specific disputes about state law after the Special Master issues a revised R&R.

The primary task upon remand is to conduct a survey of the relevant laws of each state with respect to each claim asserted in the Med Mon Master complaint. The Special Master should provide a roadmap for a ruling on the motion to dismiss which identifies, for each count and each state, the claims that will survive.

To the extent that certain claims present similar issues, the analysis may be combined. For example, all the tort claims for each state (counts I-III, V-IX and XIII) may include, as an element of the prima facie case, injury. The question will be, for each state, whether economic harm or subcellular harm will satisfy that element. The Special Master should also identify which claims survive in those states that have abandoned the manifest physical injury requirement.

Similarly, the breach of warranty claims in counts X-XII may present common questions about whether the elements of those claims are sufficiently pleaded, i.e., whether factual allegations about economic harm or subcellular change are sufficient.

For the stand-alone medical monitoring claims in count IV, the Special Master should identify which state subclasses remain. The Special Master should also address whether the relevant state requires a physical harm; and, if so, whether subcellular change is sufficient.

For the product liability acts claims (count XIV), it will likely be necessary, as an initial matter, for plaintiffs to identify each state product liability statute under which they seek medical monitoring. The Special Master will need to examine the statutory language and applicable caselaw to determine whether injury or harm is a necessary element of the claim, and, if so, whether economic harm is enough and, if not, whether subcellular change would be sufficient to plead a physical injury.

The court notes that the Special Master understood that plaintiffs did not contest Respironics' caselaw citations that the laws of 31 jurisdictions do not recognize negligence-based entitlement to medical monitoring in the absence of manifest physical injury (ECF No. 2273 at 7). In their objections, however, plaintiffs correctly point out that they did, in fact, contest that caselaw (ECF No. 2314 at 9 & Ex. A, B). The Special Master should revisit those

disputes. With respect to Colorado, Kansas and Ohio, the Special Master should examine the strength of the analysis in the federal court decisions cited by plaintiffs to determine whether they provide a clear indication of state law about the physical injury requirement, as discussed above.

In summary, it will be important for the court and parties to know exactly which of the 15 counts (and claims stated in them) in the Med Mon Master complaint remain in the case, and which claims apply to which states. The Special Master should clarify for each relevant state: (a) whether medical monitoring is a stand-alone claim (and whether or not a manifest physical injury is required); and (b) whether any other claim provides a basis for medical monitoring relief.

IV. Conclusion

The Special Master's R&R (ECF No. 2273) is not adopted. The matter will be remanded for further consideration and the issuance of a revised report and recommendation. The Special Master may require further briefing by the parties and, if so, the Special Master should enter a scheduling order for the briefing on the docket. All briefs must be filed on the docket. Respironics' motion to dismiss the Med Mon Master complaint (ECF No. 1345) is taken under advisement pending the remand.

An appropriate order will be entered.

BY THE COURT:

/s/ Joy Flowers Conti
Joy Flowers Conti
Senior United States District Court Judge